OCT - 2 2001

510(k) Summary

Florence Medical Ltd.

SmartFlow™

510(k) Number K 012947

Submitter's Name:
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Contact Person:
Shoshana Friedman, RAC
Push-Med Ltd.
117, Ahuza St., Ra'ananna 43373, Israel
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Trade Name:
SmartFlow™

Classification Name:
Computer, Diagnostic, Programmable

Classification:
Computer, Diagnostic, Programmable are class II devices (Product Code DQK).

Predicate Device:
The SmartFlow™ with the Multiple Lesion software is substantially equivalent to the SmartFlow™ (Florence Medical Ltd.) cleared under K003122.

Indication for use:

Florence Medical Ltd. SmartFlow™ is intended for use in coronary and peripheral vasculature in conjunction with pressure measurement devices during and after diagnostic procedures, such as angiography, or interventional procedures, such as angioplasty, to evaluate the hemodynamic status of the diseased arteries and to provide further clinical information in the diagnosis and treatment of both coronary and peripheral artery diseases.

Device Description:

The SmartFlow™ with the Multiple Lesion software is a tool for measuring coronary and peripheral vasculature hemodynamic status patterns during diagnostic and interventional procedures.

The SmartFlow™ is a PC based system comprising of a full color display with a touchscreen for patient data entry and control, and software calculations of the CFR and FFR parameters. The display and touchscreen are mounted in a shielded metal housing.

The SmartFlow™ may be operated through its touchscreen or through an Infra-red receiver port which allows the use of a hand-held remote.

There are two defined accessories for use with the device: *Monitor interface* for standard medical monitors and *hand-held Infrared remote control* which activates function keys and acts as a mouse.

Substantial Equivalence:

The SmartFlow™ with the Multiple Lesion software is substantially equivalent to the SmartFlow™. In fact, it is an improved model of the SmartFlow™ that enables analysis of multiple lesion cases as well as single lesion cases.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 2 2001

Mr. Shoshana Friedman
Managing Director
Florence Medical Ltd.
c/o Push-Med Ltd.
117 Ahuzah Street
Ra'ananna 43373, Israel

Re: K012947
Trade Name: SmartFlow™
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable dianostic computer.
Regulatory Class: II
Product Code: DQK
Dated: August 25, 2001
Received: September 4, 2001

Dear Mr. Friedman,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number: K012947

Device Name: SmartFlow™

Indications for Use:

The SmartFlow™ is intended for use in coronary and peripheral vasculature in conjunction with pressure measurement devices during and after diagnostic procedures, such as angiography, or interventional procedures, such as angioplasty, to evaluate the hemodynamic status of the diseased arteries and to provide further clinical information in the diagnosis and treatment of both coronary and peripheral artery diseases.

(PLEASE DO NOT WRITE BELOW THIS LINE -CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K012947

Prescription Use ✓ OR Over the Counter Use_____
(Per 21 CFR 801.109)